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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/737,328 | 12/16/2003 | Satoru Kuhara | JG-YY-4946D-C/500569. | 6127 |

26418 7590 03/17/2005

REED SMITH, LLP
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| EXAMINER | |
|---|---|
| LU, FRANK WEI MIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1634 | |

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/737,328 | KUHARA ET AL. | |
| | Examiner | Art Unit | |
| | Frank W Lu | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/499,717.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's response to the office action filed on December 16, 2004 has been entered. The claims pending in this application are claims 14-25. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on December 16, 2004.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 14 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown *et al.,* (US Patent No. 5,807,522, filed on June 7, 19995).

Note that this rejection is based on that one of lambda clone PCR products are considered as a hydrophilic polymer since lambda clone products are water-soluble.

Regarding claims 14 and 16-19, since Brown *et al.,* teach to load 1 μl of the concentrated lambda clone PCR product in 3 ×SSC directly from 96 well storage plates into the open capillary printing element and deposit about ~5 nl of sample per glass slide at 380 micron spacing between spots, on each of 40 slides wherein the slides are coated with a layer of poly-l-lysine (see column 16) and claim 14 does not require that a hydrophilic polymer and a compound must be different,

Brown *et al.,* disclose spotting an aqueous solution containing a hydrophilic polymer (ie., the concentrated lambda clone PCR product) and a compound selected from the group consisting of the oligonucleotide and polynucleotide (ie., the concentrated lambda clone PCR product) onto the solid carrier (ie., the glass slide) whereby fixing the compound to the solid carrier by electrostatic bonding (ie., by the interaction between the concentrated lambda clone PCR product with negative charges and poly-l-lysine with positive charges) wherein the solid carrier is a glass sheet pre-treated with poly-l-lysine as recited in claims 14 and 17-19. Since Brown *et al.,* teach that, after the spotting operation is complete, the slides are rehydrated in a humid chamber for 2 hours, baked in a dry 80° C vacuum oven for 2 hours, rinsed to remove unabsorbed DNA, and then treated with succinic anhydride to reduce non-specific adsorption of the labeled hybridization probe to the poly-l-lysine coated glass surface and immediately prior to use, the immobilized DNA on the array is denatured in distilled water at 90°C for 2 minutes (see column 16), Brown *et al.,* disclose washing the carrier (ie., rinsing to remove unabsorbed DNA), drying the carrier (ie., baking in a dry 80°C vacuum oven), and heating the carrier as recited in claim 14 wherein washing the carrier resulting from the spotting step and drying the carrier resulting from the washing step prior to heating the carrier (ie., incubating the array at 90°C for 2 minutes) as recited in claim 16.

Regarding claim 20, since the slides taught by Brown *et al.,* are coated with a layer of poly-l-lysine (containing amino groups), Brown *et al.,* disclose that the glass sheet is pre-treated with a silane coupling agent having an amino group (ie., poly-l-lysine).

Therefore, Brown *et al.,* teach all limitations recited in claims 14 and 16-20.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14, 16-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.*, (1995) in view of Rudolph (EP 320842 A2, published on December 12, 1988).

Note that this rejection is based on that a hydrophilic polymer is different from one of lambda clone PCR products.

Regarding claims 14 and 16-19, since Brown *et al.*, teach to load 1 μl of the concentrated lambda clone PCR product in 3 ×SSC directly from 96 well storage plates into the open capillary printing element and deposit about ~5 nl of sample per glass slide at 380 micron spacing between spots, on each of 40 slides wherein the slides are coated with a layer of poly-l-lysine (see column 16), Brown *et al.*, disclose spotting an aqueous solution containing a compound selected from the

group consisting of the oligonucleotide and polynucleotide (ie., the concentrated lambda clone PCR product) onto the solid carrier (ie., the glass slide) whereby fixing the compound to the solid carrier by electrostatic bonding (ie., by the interaction between the concentrated lambda clone PCR product with negative charges and poly-l-lysine with positive charges) wherein the solid carrier is a glass sheet pre-treated with poly-l-lysine as recited in claims 14 and 17-19. Since Brown *et al.*, teach that, after the spotting operation is complete, the slides are rehydrated in a humid chamber for 2 hours, baked in a dry 80°C vacuum oven for 2 hours, rinsed to remove unabsorbed DNA, and then treated with succinic anhydride to reduce non-specific adsorption of the labeled hybridization probe to the poly-l-lysine coated glass surface and immediately prior to use, the immobilized DNA on the array is denatured in distilled water at 90°C for 2 minutes (see column 16), Brown *et al.*, disclose washing the carrier (ie., rinsing to remove unabsorbed DNA), drying the carrier (ie., baking in a dry 80° C vacuum oven), and heating the carrier as recited in claim 14 wherein washing the carrier resulting from the spotting step and drying the carrier resulting from the washing step prior to heating the carrier (ie., incubating the array at 90°C for 2 minutes) as recited in claim 16.

Regarding claim 20, since the slides taught by Brown *et al.*, are coated with a layer of poly-l-lysine (containing amino groups), Brown *et al.*, disclose that the glass sheet is pre-treated with a silane coupling agent having an amino group (ie., poly-l-lysine).

Brown *et al.*, do not disclose an aqueous solution containing a hydrophilic polymer and a compound selected from the group consisting of the oligonucleotide and polynucleotide as recited in claim 14 wherein the hydrophilic polymer is a nonionic polymer or a cationic polymer as recited in claim 22 and hydrophilic polymer is a cellulose derivative as recited in claim 23,

wherein the hydrophilic polymer is selected from the group consisting of polyacrylamide, polyethylene glycol, polyvinyl alcohol and saccharide as recited in claim 24, and wherein the aqueous solution contains the hydrophilic polymer in an amount of 0.1 to 2.0 vol. % as recited in claim 25.

Regarding claims 14 and 22-25, since Rudolph teaches to load RNA or DNA probes with a binding aid onto a solid support and teaches that useful binding aids includes cellulose derivatives, starch, and polysaccharides and 1% binding aid solution is suitable (see columns 2-4), Rudolph disclose an aqueous solution containing a hydrophilic polymer and a compound selected from the group consisting of the oligonucleotide and polynucleotide as recited in claim 14 wherein the hydrophilic polymer is a nonionic polymer (ie., starch, see the specification, page 8, second paragraph) as recited in claim 22 and hydrophilic polymer is a cellulose derivative as recited in claim 23, wherein the hydrophilic polymer is selected from the group consisting of polyacrylamide, polyethylene glycol, polyvinyl alcohol and saccharide as recited in claim 24, and wherein the aqueous solution contains the hydrophilic polymer in an amount of 0.1 to 2.0 vol. % (ie., 1% binding aid solution) as recited in claim 25.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted an aqueous solution containing a hydrophilic polymer (ie., a binding aid) and a compound selected from the group consisting of the oligonucleotide and polynucleotide onto the solid carrier as recited in claim 14 in view of the prior art of Brown *et al.*, and Rudolph. One having ordinary skill in the art would have been motivated to do so because Rudolph has successfully loaded RNA or DNA probes with a binding aid onto a solid support and suggests that "the binding aids of this invention do not themselves attach or link the biological agent to the support, but serve to localize the biological agent so that

it becomes immobilized in the desired position. This localization also ensures that the entire deposited quantity of biological agent is immobilized on the support" (see column 3, second paragraph). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to spot an aqueous solution containing a hydrophilic polymer (ie., a binding aid) and a compound selected from the group consisting of the oligonucleotide and polynucleotide onto the solid carrier during the process for performing the method recited in claim 14.

6. Claims 14 and 21are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.,* (1995) as applied to claims 14 and 17-20 above, and further in view of Running *et al.,* (BioTechniques, 8, 276 and 279, 1990).

The teachings of Brown *et al.,* have been summarized previously, *supra.*

Brown *et al.,* do not disclose that the oligonucleotide or the polynucleotide is fixed to the solid carrier at its one end portion as recited in claim 15 and the oligonucleotide or the polynucleotide has a functional group selected from the group consisting of an amino group, an aldehyde group, a thiol group and a biotin group as recited in claim 21.

Running *et al.,* teach to couple a nucleic acid having an aldehyde group to a solid support coated with poly-l-lysine (see pages 276 and 279).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the methods recited in claims 15 and 21 wherein the oligonucleotide or the polynucleotide is fixed to the solid carrier at its one end portion as recited in claim 15 and the oligonucleotide or the polynucleotide has an aldehyde group in view of the prior art of Brown *et al.,* and Running *et al.*. One having ordinary skill in

the art would have been motivated to do so because Running *et al.,* have successfully coupled a nucleic acid having an aldehyde group to a solid support coated with poly-l-lysine and the simple replacement of one well known coupling method (i.e., direct loading taught by Brown *et al.,*) from another well known coupling method (i.e., the coupling method taught by Running *et al.,*) during the process for performing the method recited in claims 15 and 21 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the coupling method taught by Running *et al.,* would enhance stability of the nucleic acid immobilized on the solid support (a nucleic acid having an aldehyde group forms a complex with poly-l-lysine on the solid support).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claims 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown *et al.,* (1995) in view of Rudolph (1988) as applied to claims 14, 16-20, and 22-25 above, and further in view of Running *et al.,* (1990).

The teachings of Brown *et al.,* and Rudolph have been summarized previously, *supra.*

Brown *et al.*, and Rudolph do not disclose that the oligonucleotide or the polynucleotide is fixed to the solid carrier at its one end portion as recited in claim 15 and the oligonucleotide or the polynucleotide has a functional group selected from the group consisting of an amino group, an aldehyde group, a thiol group and a biotin group as recited in claim 21.

Running *et al.*, teach to couple a nucleic acid having an aldehyde group to a solid support coated with poly-l-lysine (see pages 276 and 279).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the methods recited in claims 15 and 21 wherein the oligonucleotide or the polynucleotide is fixed to the solid carrier at its one end portion as recited in claim 15 and the oligonucleotide or the polynucleotide has an aldehyde group in view of the prior art of Brown *et al.*, Rudolph and Running *et al.*. One having ordinary skill in the art would have been motivated to do so because Running *et al.*, have successfully coupled a nucleic acid having an aldehyde group to a solid support coated with poly-l-lysine and the simple replacement of one well known coupling method (i.e., direct loading taught by Brown *et al.*,) from another well known coupling method (i.e., the coupling method taught by Running *et al.*,) during the process for performing the method recited in claims 15 and 21 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the coupling method taught by Running *et al.*, would enhance stability of the nucleic acid immobilized on the solid support (a nucleic acid having an aldehyde group forms a complex with poly-l-lysine on the solid support).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their

expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 14, 2005

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

3/15/05